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May 18, 2004

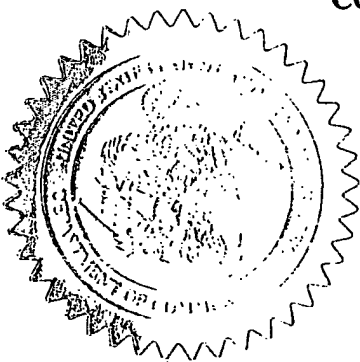
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THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK
OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT
APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
FILING DATE.

APPLICATION NUMBER: 10/406,336

FILING DATE: April 03, 2003

RELATED PCT APPLICATION NUMBER: PCT/US04/09471

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS



T. LAWRENCE
Certifying Officer

PRIORITY DOCUMENT
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04/03/03
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04-04-03 10406336 040303

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Approved for use through 10/31/2002. OMB 0651-0032
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No. _____
First Inventor Glenn Wakefield
Title Magnetically Propelled Capsule Endoscopy
Express Mail Label No. E188230355US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. ☒ Applicant claims small entity status.
See 37 CFR 1.27.
3. ☒ Specification [Total Pages]
(preferred arrangement set forth below)
 - Descriptive title of the invention
 - Cross Reference to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to sequence listing, a table, or a computer program listing appendix
 - Background of the invention
 - Brief Summary of the invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
4. ☐ Drawing(s) (35 U.S.C. 113) [Total Sheets]
5. Oath or Declaration [Total Pages]
 - a. ☒ Newly executed (original or copy)
 - b. ☐ Copy from a prior application (37 CFR 1.63 (d))
(for continuation/divisional with Box 18 completed)
 - i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - a. ☐ Computer Readable Form (CRF)
 - b. Specification Sequence Listing on:
 - i. ☐ CD-ROM or CD-R (2 copies); or
 - ii. ☐ paper
 - c. ☐ Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement (when there is an assignee) ☐ Power of Attorney
11. ☐ English Translation Document (if applicable)
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☐ Return Receipt Postcard (MPEP 503) (Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)
16. ☐ Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☐ Other: _____

18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP)

of prior application No. _____

Prior application information:

Examiner _____

Group Art Unit: _____

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

☐ Customer Number or Bar Code Label

or ☒ Correspondence address below

Name Glenn Wakefield
Address 1416 East Carmen Street
City Tempe State AZ Zip Code 85283
Country USA Telephone 480-839-7094 Fax _____

Name (Print/Type) Glenn Wakefield Registration No. (Attorney/Agent) _____
Signature Glenn Wakefield Date 04/03/2003

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**FEE TRANSMITTAL
for FY 2003**

Effective 01/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT

(\$)

Complete if Known

Application Number

Filing Date

First Named Inventor

Glenn Wakefield

Examiner Name

Art Unit

Attorney Docket No.

METHOD OF PAYMENT (check all that apply)☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None☐ Deposit Account:Deposit
Account
Number
Deposit
Account
Name

The Commissioner is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Credit any overpayments☐ Charge any additional fee(s) during the pendency of this application☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

| Large Entity Fee Code (\$) | Small Entity Fee Code (\$) | Fee Description | Fee Paid |
|-------------------------------|-------------------------------|------------------------|----------|
| 1001 750 | 2001 375 | Utility filing fee | 375 |
| 1002 330 | 2002 165 | Design filing fee | |
| 1003 520 | 2003 260 | Plant filing fee | |
| 1004 750 | 2004 375 | Reissue filing fee | |
| 1005 160 | 2005 80 | Provisional filing fee | |

SUBTOTAL (1) (\$ 375)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

| Total Claims | Extra Claims | Fee from below | Fee Paid |
|--------------------|--------------|----------------|----------|
| Independent Claims | -20** = | X | |
| Multiple Dependent | -3** = | X | |

| Large Entity Fee Code (\$) | Small Entity Fee Code (\$) | Fee Description |
|-------------------------------|-------------------------------|--|
| 1202 18 | 2202 9 | Claims in excess of 20 |
| 1201 84 | 2201 42 | Independent claims in excess of 3 |
| 1203 280 | 2203 140 | Multiple dependent claim, if not paid |
| 1204 84 | 2204 42 | ** Reissue independent claims over original patent |
| 1205 18 | 2205 9 | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) (\$ 0)

**or number previously paid, if greater, For Reissues, see above

FEE CALCULATION (continued)**3.. ADDITIONAL FEES**

Large Entity Small Entity

| Fee Code (\$) | Fee Code (\$) | Fee Description | Fee Paid |
|---------------|---------------|--|----------|
| 1051 130 | 2051 65 | Surcharge - late filing fee or oath | |
| 1052 50 | 2052 25 | Surcharge - late provisional filing fee or cover sheet | |
| 1053 130 | 1053 130 | Non-English specification | |
| 1812 2,520 | 1812 2,520 | For filing a request for ex parte reexamination | |
| 1804 920* | 1804 920* | Requesting publication of SIR prior to Examiner action | |
| 1805 1,840* | 1805 1,840* | Requesting publication of SIR after Examiner action | |
| 1251 110 | 2251 55 | Extension for reply within first month | |
| 1252 410 | 2252 205 | Extension for reply within second month | |
| 1253 930 | 2253 465 | Extension for reply within third month | |
| 1254 1,450 | 2254 725 | Extension for reply within fourth month | |
| 1255 1,970 | 2255 985 | Extension for reply within fifth month | |
| 1401 320 | 2401 160 | Notice of Appeal | |
| 1402 320 | 2402 160 | Filing a brief in support of an appeal | |
| 1403 280 | 2403 140 | Request for oral hearing | |
| 1451 1,510 | 1451 1,510 | Petition to institute a public use proceeding | |
| 1452 110 | 2452 55 | Petition to revive - unavoidable | |
| 1453 1,300 | 2453 650 | Petition to revive - unintentional | |
| 1501 1,300 | 2501 650 | Utility issue fee (or reissue) | |
| 1502 470 | 2502 235 | Design issue fee | |
| 1503 630 | 2503 315 | Plant issue fee | |
| 1460 130 | 1460 130 | Petitions to the Commissioner | |
| 1807 50 | 1807 50 | Processing fee under 37 CFR 1.17(q) | |
| 1806 180 | 1806 180 | Submission of Information Disclosure Stmt | |
| 8021 40 | 8021 40 | Recording each patent assignment per property (times number of properties) | |
| 1809 750 | 2809 375 | Filing a submission after final rejection (37 CFR 1.129(a)) | |
| 1810 750 | 2810 375 | For each additional invention to be examined (37 CFR 1.129(b)) | |
| 1801 750 | 2801 375 | Request for Continued Examination (RCE) | |
| 1802 900 | 1802 900 | Request for expedited examination of a design application | |

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 0)

SUBMITTED BY

Name (Print/Type)

Glenn Wakefield

Registration No.
(Attorney/Agent)

(Complete if applicable)

Telephone

480-839-7094

Signature

Glenn Wakefield

Date

04/03/2003

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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TITLE OF INVENTION

Magnetically Propelled Capsule Endoscopy

CROSS-REFERENCE TO RELATED APPLICATIONS

Not Applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

REFERENCE TO SEQUENCE LISTING, A TABLE, OR A COMPUTER PROGRAM LISTING COMPACT DISC APPENDIX

Not Applicable

BACKGROUND OF THE INVENTION

This patent application applies to the field of medical imaging and tissue biopsy/excision.

Traditionally the digestive tract has been examined by the upper gastrointestinal endoscope and the lower gastrointestinal endoscope and most recently by the capsule endoscope. Upper and lower gastrointestinal endoscopy usually require an anesthetic and are limited by the inability to examine the small intestine. Capsule endoscopy does not practically allow for real time imaging and precludes tissue biopsy/excision. The upper and lower gastrointestinal endoscopy and capsule endoscopy provide a limited range of viewing/access angles.

BRIEF SUMMARY OF THE INVENTION

Magnetically propelled capsule endoscopy provides for the medical examination of the gastrointestinal tract. After the capsule is swallowed, it will be steered throughout the gastrointestinal tract by an externally generated magnetic field. This device will provide real time imagery and position data along with the ability to perform tissue biopsy/excision. This device can be applied to the gastrointestinal tract, reproductive tract, trachea/lungs, vascular system or any accessible body cavity.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING

Not Applicable

DETAILED DESCRIPTION OF THE INVENTION

Magnetically propelled capsule endoscopy allows for a fast, comprehensive medical examination of the digestive tract, reproductive tract, trachea/lungs, vascular system or any accessible body cavity. The capsule is swallowed or appropriately placed in the body. Contained within the small capsule will be:

(#1 possibility) - magnets for movement and directional control; LEDs for lighting and camera for visualization; rf source and receiver to transmit pictures and to communicate; gyroscope/accelerometer for positional information; mechanical equipment for tissue biopsy/excision or other procedures; power source; electronics;

(#2 possibility) - magnets for movement and directional control; fiber optic light source, fiber optic imaging lens, power lines, communication lines, air hose, and water hose extending out the back of the capsule and connecting to the external control instrument; gyroscope/accelerometer for positional information; mechanical equipment for tissue biopsy/excision or other procedures; electronics.

All of the parts in #1 possibility and #2 possibility, other than the magnets, will be composed of nonmagnetic material or magnetically shielded as required. The #1 possibility is a capsule with no physical connection to the outside in contrast to the #2 possibility that is a capsule that has a physical connection to the outside. The choice of physical connection or not, capsule size and capabilities will vary depending on the part of the body that is being examined by the medical practitioner.

The magnets contained within the capsule will be bathed in an externally generated magnetic field. The external field is created by inscribing six metal rings on the six faces of an imaginary cube. Current is running through each of the six rings which effectively allows a pair of rings to control each dimension. The metal rings are composed of many windings of appropriately coated wire. The patient undergoing the medical examination will be placed inside the six ringed

structure. The capsule will be moved by appropriately changing the current within each ring. As necessary, the actual rings will be moved in conjunction with the changing current. The medical practitioner, using visual feedback, will guide the capsule throughout the body part under examination. The magnetic field strength will be adjusted appropriately for direction change, movement or extra stationary stability for tissue biopsy/excision or other procedures.

The gyroscope/accelerometer will provide the ability to map in real time the positional progress of the capsule. A positional map will be created of the entire exam, areas of interest can be marked, and visual images will be generated corresponding to each positional location of the capsule. A computer generated three dimensional fly through can be created based on the data collected from the examination. All of this data can be appropriately stored for future reference and for comparison with other medical exams.

CLAIMS

I claim:

1. Magnetically propelled capsule endoscopy allows for a fast, comprehensive medical examination of the digestive tract, reproductive tract, trachea/lungs, vascular system or any accessible body cavity. The capsule is swallowed or appropriately placed in the body. Contained within the small capsule will be:

(#1 possibility) - magnets for movement and directional control; LEDs for lighting and camera for visualization; rf source and receiver to transmit pictures and to communicate; gyroscope/accelerometer for positional information; mechanical equipment for tissue biopsy/excision or other procedures; power source; electronics;

(#2 possibility) - magnets for movement and directional control; fiber optic light source, fiber optic imaging lens, power lines, communication lines, air hose, and water hose extending out the back of the capsule and connecting to the external control instrument; gyroscope/accelerometer for positional information; mechanical equipment for tissue biopsy/excision or other procedures; electronics.

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ABSTRACT OF THE DISCLOSURE

Magnetically propelled capsule endoscopy provides for the medical examination of the gastrointestinal tract. After the capsule is swallowed, it will be steered throughout the gastrointestinal tract by an externally generated magnetic field. This device will provide real time imagery and position along with the ability to perform tissue biopsy/excision. This device can be applied to the gastrointestinal tract, reproductive tract, trachea/lungs, vascular system or any accessible body cavity.

PTO/SB/01 (10-01)

Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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| | | |
|---|------------------------|-----------------|
| DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63) <input checked="" type="checkbox"/> Declaration Submitted with Initial Filing OR <input type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required) | Attorney Docket Number | |
| | First Named Inventor | Glenn Wakefield |
| | COMPLETE IF KNOWN | |
| | Application Number | / |
| | Filing Date | |
| | Art Unit | |
| | Examiner Name | |

As the below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Magnetically Propelled Capsule Endoscopy

(Title of the Invention)

the specification of which

☒ is attached hereto

OR

☐ was filed on (MM/DD/YYYY)

as United States Application Number or PCT International

Application Number and was amended on (MM/DD/YYYY)

(if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

| Prior Foreign Application Number(s) | Country | Foreign Filing Date (MM/DD/YYYY) | Priority Not Claimed | Certified Copy Attached? | |
|-------------------------------------|---------|----------------------------------|--------------------------|--------------------------|--------------------------|
| | | | | YES | NO |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| | | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

[Page 1 of 2]

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DECLARATION — Utility or Design Patent ApplicationDirect all correspondence to: ☐ Customer Number or Bar Code Label ☐ OR ☒ Correspondence address belowName Glenn WakefieldAddress 1416 East Carmen StreetCity TempeState AZZIP 85283Country USATelephone 480-839-7094

Fax

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NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventorGiven Name
(first and middle [if any]) Glenn MarkFamily Name
or Surname WakefieldInventor's
Signature Glenn Mark WakefieldDate 04/03/2003Residence: City TempeState AZCountry USACitizenship USAMailing Address 1416 East Carmen StreetCity TempeState AZZIP 85283Country USANAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventorGiven Name
(first and middle [if any])Family Name
or SurnameInventor's
Signature

Date

Residence: City

State

Country

Citizenship

Mailing Address

City

State

ZIP

Country

☐ Additional inventors are being named on the _____ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.